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QuantiFERON®-TB Update:

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CDC Guidelines Now Available for *QuantiFERON®-TB*

Dear Colleague,

I am pleased to inform you that the Centers for Disease Control and Prevention (CDC) guidelines for the use of **QuantiFERON®-TB** are now available. The MMWR can be downloaded from the CDC website at www.cdc.gov/mmwr. The guidelines endorse the use of QuantiFERON®-TB in a wide range of subjects and settings, and suggest procedures for incorporating QuantiFERON®-TB testing in TB programs that can lead to more effective TB treatment and overall improved TB control.

The interim recommendations incorporate QuantiFERON®-TB into the CDC targeted testing approaches, and recommend QuantiFERON®-TB testing for a number of situations, including LTBI screening for health care workers, recent immigrants, injection drug users, prison and jail inmates and employees, entrance requirements for schools and workplaces, and military personnel. The guidelines note the advantages of QuantiFERON®-TB in requiring a single subject contact, having no booster effect, and importantly the reduction of reader bias and error. Key aspects of the guidelines are explained below.

Screening of Persons at Low-Risk for LTBI:

Targeted testing does not include TB screening of low risk individuals in general, but the CDC does note that it is often performed due to occupational requirements, such as military recruit screening or for some employment screening.

An important point made by the CDC is that true TB infection is most likely when both QuantiFERON®-TB and TST responses are positive. This opens new possibilities in LTBI diagnosis, particularly in low-risk subjects where TB infection is uncommon.

The CDC suggests that QuantiFERON®-TB can be used as an initial screen for TB infection in low-risk groups and all negatives excluded from follow-up. The CDC then recommend that those QuantiFERON®-TB positive be tested with the TST and that only those positive to both tests be offered prophylaxis for LTBI after exclusion of active TB (the reverse order of testing is not possible as the TST provokes immune stimulation and compromises future testing).

Confirmation should provide much greater confidence in applying LTBI therapy in low-risk subjects over use of TST alone, with little to no increase in logistic cost. Importantly, it will result in cost savings and health improvement by reducing the burden of needless treatment and medical procedures, allowing identification and treatment of the truly infected and reducing the risk of unnecessary drug-induced hepatitis.



Screening of Persons at High-Risk for LTBI:

The CDC recommends initial screening by QuantiFERON®-TB of persons at increased risk for LTBI, including recent immigrants, injection-drug users, and inmates and staff of correctional facilities.

For those individuals at increased risk for LTBI, predictive accuracy of testing is higher. Treatment for LTBI can be initiated on the basis of a positive QuantiFERON®-TB result, using clinical judgment, once active TB has been ruled out. Confirmation of a positive QuantiFERON®-TB result with a TST is not a CDC requirement for this group, although as QuantiFERON®-TB does not affect the immune system a TST can be done.

At this time the CDC has not recommended QuantiFERON®-TB in contact tracing following immediate exposure or for active TB suspects. CDC hesitation in recommending QuantiFERON®-TB for these applications may derive from perceptions on the sensitivity of QuantiFERON®-TB in untreated active TB (the most important target in contact tracing). Published data on active TB cases is derived from studies with people undergoing (or who had completed) TB treatment. Both IFN- γ and TST responses can be absent in patients with active TB, but TST responses rapidly turn positive after initiation of treatment. Recent studies have investigated the sensitivity of both tests in untreated people with active TB and found QuantiFERON-TB to be more sensitive than the TST. Once these studies are published we trust that the CDC will review their guidelines with respect to contact tracing and active TB.

Another study, recently conducted in Europe, indicates that QuantiFERON®-TB should prove valuable in contact tracing, as it showed interferon responses as measured by QuantiFERON®-TB accord closely to TB exposure risk, whereas TST responses do not. We expect publication of this data soon.

For further information regarding QuantiFERON®-TB please do not hesitate to contact Cellestis customer service at **800.519.4627** or email: **customer.service@cellestis.com**

Sincerely,

Mark Boyle
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